EVERYWAY EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

FEB - 1 2012

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at June 15, 2011.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:

   Establishment:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : tu922@ms35.hinet.net

2. Name of the Device:
   Everyway Traction Unit, model EVER-TRAC ET-800.

3. Information of the 510(k) Cleared Device (Predicate Device):
   Ever Prosperous Traction System model DIGIT-TRAC 930(K052453)

4. Classification Information:
   Trade/Device Name: Everyway Traction Unit, model EVER-TRAC ET-800.
   Regulation Number: 21 CFR Part 890.5900
   Regulation Name: Powered Traction Equipment
   Regulatory Class: II
   Product Code: ITH

5. Device Description:
   Everyway Traction Unit, model EVER-TRAC ET-800 is a medical device constructed for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

   For this intended operation function, ET-800 is the combination of driving moter, speed reduction gear, pulley assembly, spring, force and speed control unit...etc. All of the operational parts as above mentioned are mounted on the frame of device housing.

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The pulling force for ET-800 is generated by the combination of induction motor and speed reduction gear. For the operation of ET-800, the single phase AC power shall be supplied from the general wall socket of house (Note: In USA, the power supply specification is single phase, 60Hz, 120V).

Basically ET-800 is a microprocessor-controlled traction system in which the operational software is built inside the control unit to properly control the exertion and release of pulling force according to the setting for applying force, operation cycle, and operation time prescribed by the physician.

To ensure the safety of operation, the device was designed and constructed to provide the following safety protection: <1> Manual release, <2>Auto shutdown, and <3>Safe protect. In addition, the device also provides warning alarm function for same near dangerous situations as mentioned in user's manual.

6. Intended Use:
The Everyway Traction System, model EVER-TRAC ET-800 is intended for medical purpose for use in conjunction with traction accessories, such as belts and harnesses , to exert therapeutic pulling forces on the patient's body

7. Comparison to the 510(k) Cleared Device (Predicate Device):
The Everyway Traction Unit, model EVER-TRAC ET-800 is substantially equivalent to the Ever Prosperous Traction System model DIGIT-TRAC 930(K052453) without any significant difference in main technological and operational feature.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of EVER-TRAC ET-800 are as the followings:
1> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
2> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:
No particular Clinical Test was conducted for Everyway Traction Unit, model EVER-TRAC ET-800.

10. Conclusions
The Everyway Traction Unit, model EVER-TRAC ET-800, has the same intended use and technological characteristics as the cleared device of Ever Prosperous Traction System model DIGIT-TRAC 930(K052453. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

In the other words, Everyway Traction Unit, model EVER-TRAC ET-800 is substantial equivalent with the Ever Prosperous Traction System model DIGIT-TRAC 930(K052453) .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 1 2012

Everyway Medical Instruments Co., Ltd.
% Mansour Consulting LLC
Mr. Jay Mansour
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K112074
Trade/Device Name: Everyway Traction Unit, Model EVER-TRAC ET-800
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: December 30, 2011
Received: January 03, 2012

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EVERYWAY EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

Indications For Use

510(k) Number (if known):_____.

Device Name: Everyway Traction Unit, model EVER-TRAC ET-800.

Indications For Use:

The Everyway Traction System, model EVER-TRAC ET-800 is intended for medical purpose for use in conjunction with traction accessories, such as belts and harnesses , to exert therapeutic pulling forces on the patient's body.

Prescription Use __√__ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112074